

U.S. Appln. S.N. 10/534,091
AMENDMENT

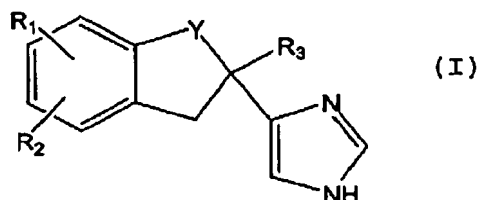
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IN THE CLAIMS:

Please amend claims 11, 14 and 19, and add new claims 23-32, as shown below in the detailed listing of all claims which are, or were, in this application:

Claims 1-10 (Canceled).

11. (Currently amended) An oromucosal formulation comprising as an active ingredient a substituted imidazole derivative of conforming to formula (I)



where Y is -CH₂- or -CO-, R₁ is halogen or hydroxy, R₂ is H or halogen and R₃ is H or lower alkyl, or an acid addition salt thereof, in combination with at least one oromucosally acceptable preserving agent, at least one flavoring agent or a mixture thereof.

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12. (Previously presented) The formulation of claim 11, wherein the active ingredient is 4-(2-ethyl-5-fluoro-indan-2-yl)-1H-imidazole or its acid salt.

13. (Previously presented) The formulation of claim 12, wherein said active ingredient is a hydrochloride salt of 4-(2-ethyl-5-fluoro-indan-2-yl)-1H-imidazole.

14. (Currently amended) The formulation of claim 11, further comprising at least one ~~additive selected from the group consisting of solvents, oromucosally acceptable solvent preserving agents, flavoring agents and mixtures thereof.~~

15. (Previously presented) The formulation of claim 14, wherein the solvent is selected from the group consisting of ethanol, water and a mixture thereof.

16. (Previously presented) The formulation of claim 14, wherein the preserving agent is selected from the group consisting of methyl parahydroxybenzoate, propyl parahydroxybenzoate and a mixture thereof.

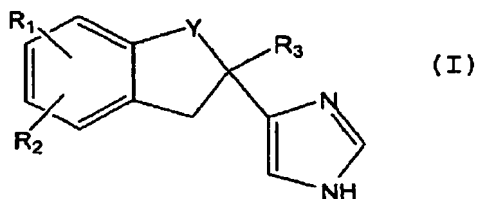
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17. (Previously presented) The formulation of claim 14, wherein the flavoring agent is selected from the group consisting of aspartame, black currant and a mixture thereof.

18. (Previously presented) The formulation of claim 11, comprising the following components: (a) 4-(2-ethyl-5-fluoro-indan-2-yl)-1H-imidazole or its acid salt, (b) ethanol and water, (c) methyl parahydroxybenzoate and propyl parahydroxybenzoate, and (d) aspartame and black currant.

19. (Currently amended) The An oromucosal formulation of claim 11, comprising as an active ingredient a substituted imidazole derivative conforming to formula (I)



where Y is -CH₂- or -CO-, R₁ is halogen or hydroxy, R₂ is H or halogen and R₃ is H or lower alkyl, or an acid addition salt

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thereof, wherein the formulation is in the form of a spray, gel, a mucoadhesive buccal tablet or paste, or a sublingual tablet.

20. (Previously presented) The formulation of claim 19, wherein the formulation is in the form of a spray.

21. (Previously presented) A process for preparing a formulation according to claim 18 comprising

mixing and dissolving ethanol, purified water, methyl parahydroxybenzoate, propyl parahydroxybenzoate and aspartame at +15 to +25 °C;

followed by adding and dissolving 4-(2-ethyl-5-fluoroindan-2-yl)-1H-imidazole hydrochloride and artificial flavor, at +15 to +25 °C;

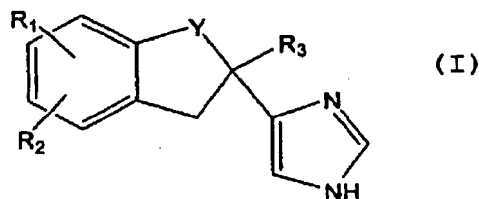
adjusting the volume of the mixture with purified water, followed by filtering and recovering the desired spray formulation.

22. (Previously presented) The process of claim 21, wherein said artificial flavor comprises black currant.

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23. (New) A method of administering a formulation comprising as an active ingredient a substituted imidazole derivative of formula (I)



where Y is -CH₂- or -CO-, R₁ is halogen or hydroxy, R₂ is H or halogen and R₃ is H or lower alkyl, or an acid addition salt thereof, comprising

administering said formulation to a patient by mucosal administration.

24. (New) The method of claim 23, wherein the active ingredient is 4-(2-ethyl-5-fluoro-indan-2-yl)-1H-imidazole or its acid salt.

25. (New) The method of claim 24, wherein said active ingredient is a hydrochloride salt of 4-(2-ethyl-5-fluoro-indan-2-yl)-1H-imidazole.

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26. (New) The method of claim 23, wherein said formulation includes at least one additive selected from the group consisting of solvents, preserving agents, flavoring agents and mixtures thereof.

27. (New) The method of claim 26, wherein the solvent is selected from the group consisting of ethanol, water and a mixture thereof.

28. (New) The method of claim 26, wherein the preserving agent is selected from the group consisting of methyl parahydroxybenzoate, propyl parahydroxybenzoate and a mixture thereof.

29. (New) The method of claim 26, wherein the flavoring agent is selected from the group consisting of aspartame, black currant and a mixture thereof.

30. (New) The method of claim 23, wherein said formulation comprises the following components: (a) 4-(2-ethyl-5-fluoro-indan-2-yl)-1H-imidazole or its acid salt, (b) ethanol and water, (c) methyl parahydroxybenzoate and propyl parahydroxybenzoate, and (d) aspartame and black currant.

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31. (New) The method of claim 23, wherein the formulation is administered in the form of a spray, gel, a mucoadhesive buccal tablet or paste, or a sublingual tablet.

32. (New) The method of claim 31, wherein the formulation is administered in the form of a spray.